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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/704,554	11/03/00	FRIEDHOFF	L 0200-0004

HM22/0703

TRANSPOTOMAC PLAZA
1033 N FAIRFAX STREET
SUITE 306
ALEXANDRIA VA 22314

EXAMINER	
JIANG,S	
ART UNIT	**PAPER NUMBER**
1617	5

DATE MAILED: 07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/704,554	FRIEDHOFF ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *29-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILD ACTION

This application claims priority to three provisional applications Serial No. 60/163,608, 60/219,435, 60/223,987.

Election/Restrictions

Applicant's election **without** traverse of the invention of Group I, claims 25-28, in Paper No. 4 submitted June 4, 2001 is acknowledged.

Claims 29-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Claims 1-24 and 33 link the invention of Group I. Therefore, claims 1-28 and 33 will be examined on the merits herein.

Claim Objection

Claims 9-16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is well settled that recitation of an inherent property of a composition will not further limit claims drawn to a composition.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-28 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "APP" in claims 1-2, 17-18, 20, 23, 26, and 33 renders the claims 1-28 and 33 indefinite. The expression " APP " is not defined by the claim. The expression " APP " is indefinite as to APP encompassed thereby.

In order to expedite prosecution, claims 1-28 and 33 will be examined using the "amyloid precursor protein" as defined on page 1 of the specification as has apparently been intended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Simons et al. (AC2, PTO-1449 submitted March 7, 2001).

Simons et al. teaches that lovastatin, the HMG-CoA reductase inhibitor that is known cellular cholesterol agents, is useful in a method for treating a mammal having an APP processing disorder, e.g., Alzheimer's disease. See abstract and page 6460. Thus, Simons et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scolnick (WO 95/06470, AS1, PTO-1449 submitted March 7, 2001) in view of Sabbagh et al. (AB2, PTO-1449 submitted March 7, 2001) and May (AA2, PTO-1449 submitted March 7, 2001).

Scolnick discloses that HMG-CoA reductase inhibitor such as lovastatin, simvastatin, pravastatin, and fluvastatin is useful in a method of treating Alzheimer's disease in a human. Scolnick also discloses the effective amount of the HMG-CoA reductase inhibitor therein to be administered per day, within the instant claims, and the controlled release composition of HMG-CoA reductase inhibitor therein. See abstract, and claims 1-10. Scolnick further discloses that lovastatin, simvastatin, pravastatin, and fluvastatin that are known cellular cholesterol agents, are useful in a method for treating Alzheimer's disease. See pages 1-4, especially page 3 lines 32-34.

Scolnick do not expressly disclose a method for treating a mammal having an APP processing disorder, a method for treating a mammal having an APP processing disorder comprising lowering the amount of Aβ peptide in the brain, cerebral spinal fluid, or plasma of the mammal, a method for treating a mammal having an APP processing

disorder comprising increasing the clearance of Aβ peptide in the brain, cerebral spinal fluid, or plasma of the mammal, or a method for treating a mammal having an APP processing disorder comprising preventing or reducing Aβ peptide aggregation or plaque in the brain of the mammal by administering HMG-CoA reductase inhibitor.

Both Sabbagh et al. and May teach that Alzheimer's disease is an APP processing disorder in a mammal, associated with increasing the amount of Aβ peptide in the brain, cerebral spinal fluid, or plasma of the mammal or Aβ peptide aggregation or plaque in the brain of the mammal. See abstract and pages 1-2 and 12 of Sabbagh and entire article of May.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ HMG-CoA reductase inhibitor such as lovastatin, simvastatin, pravastatin, and fluvastatin in a method for treating a mammal having an APP processing disorder, in a method for treating a mammal having an APP processing disorder comprising lowering the amount of Aβ peptide in the brain, cerebral spinal fluid, or plasma of the mammal, in a method for treating a mammal having an APP processing disorder comprising increasing the clearance of Aβ peptide in the brain, cerebral spinal fluid, or plasma of the mammal, and in a method for treating a mammal having an APP processing disorder comprising preventing or reducing Aβ peptide aggregation or plaque in the brain of the mammal.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ HMG-CoA reductase inhibitor such as lovastatin, simvastatin, pravastatin, and fluvastatin in a method for treating a mammal having an

APP processing disorder, in a method for treating a mammal having an APP processing disorder comprising lowering the amount of Aβ peptide in the brain, cerebral spinal fluid, or plasma of the mammal, in a method for treating a mammal having an APP processing disorder comprising increasing the clearance of Aβ peptide in the brain, cerebral spinal fluid, or plasma of the mammal, and in a method for treating a mammal having an APP processing disorder comprising preventing or reducing Aβ peptide aggregation or plaque in the brain of the mammal because HMG-CoA reductase inhibitor is known to be useful in a method of treating Alzheimer's disease in a human according to Scolnick. Moreover, it is known that Alzheimer's disease is an APP processing disorder in a mammal, associated with increasing the amount of Aβ peptide in the brain, cerebral spinal fluid, or plasma of the mammal or Aβ peptide aggregation or plaque in the brain of the mammal based on the prior art. Therefore, one having ordinary skill in the art would have reasonably expected HMG-CoA reductase inhibitor to be useful in a method for treating a mammal having an APP processing disorder such as Alzheimer's disease by lowering the amount of Aβ peptide in the brain, cerebral spinal fluid, or plasma of the mammal, increasing the clearance of Aβ peptide in the brain, cerebral spinal fluid, or plasma of the mammal, or reducing Aβ peptide aggregation or plaque in the brain of the mammal.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons et al. (AC2, PTO-1449 submitted March 7, 2001).

Simons et al. teaches that lovastatin, a HMG-CoA reductase inhibitor, is useful in in a method for treating a mammal having an APP processing disorder such as Alzheimer's disease by lowering the amount of Aβ peptide in the brain of the mammal, increasing the clearance of Aβ peptide in the brain of the mammal, or reducing Aβ peptide aggregation or plaque in the brain of the mammal. See abstract and page 1.

Simons et al. does not expressly disclose that lovastatin is administered by a controlled release composition and effective amount of lovastatin to be administered per day.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer lovastatin by a controlled release composition, and to optimize effective amount of lovastatin to be administered per day.

One having ordinary skill in the art at the time the invention was made would have been motivated to administer lovastatin by a controlled release dosage form and to optimize effective amount of lovastatin to be administered per day since the determination of the dosage form and the optimization of amounts of active agents to be administered is considered well within the skill of artisan.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejection to the pending claim set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
June 21, 2001

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